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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/775,909	02/02/2001	Mark Roberts	M0975/7006 (JRV)	9660	
75	90 07/03/2002				
John R. Van Amsterdam Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue			EXAMINER		
			DUFFY, PATRICIA ANN		
Boston, MA 02	2210		ART UNIT	PAPER NUMBER	
			1645	~	
			DATE MAILED: 07/03/2002	3	

Please find below and/or attached an Office communication concerning this application or proceeding.

		A (*)		
1 ''	Application No. Applicant			
Office Action Summary	Evaminar		Group Art Unit	
	Duf	F1	1645	
—The MAILING DATE of this communication appears on the	ne cover sheet be	eneath the co	rrespondence addre	·SS
Priod fr Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPI OF THIS COMMUNICATION.	RE_O~	MONTH(S)	FROM THE MAILING	S DATE
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within If NO period for reply is specified above, such period shall, by default, expire S Failure to reply within the set or extended period for reply will, by statute, cause</li> </ul>	n the statutory minimi SIX (6) MONTHS from	um of thirty (30) do	lays will be considered tire of this communication.	
Status				
☐ Responsive to communication(s) filed on		1.10.100.000		•
☐ This action is FINAL.				
☐ Since this application is in condition for allowance except for form accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D.			the merits is closed	in
Disposition of Claims				
☑ Claim(s) 37-54		is/are p	ending in the applicat	ion.
Of the above claim(s)		is/are w	ithdrawn from consid	eration.
☐ Claim(s)	·	is/are a	llowed.	
□ Claim(s)		is/are re	ejected.	
□ Claim(s)		is/are o	bjected to.	
☑ Claim(s) 37-54	<del></del>	are sub	ject to restriction or e	lection
Application Papers		•		
☐ See the attached Notice of Draftsperson's Patent Drawing Revie	w, PTO-948.			
☐ The proposed drawing correction, filed oni		☐ disapproved		
☐ The drawing(s) filed on is/are objected to b	y the Examiner.			
☐ The specification is objected to by the Examiner.				
☐ The oath or declaration is objected to by the Examiner.				
Pri rity under 35 U.S.C. § 119 (a)-(d)				
<ul> <li>□ Acknowledgment is made of a claim for foreign priority under 35</li> <li>□ All □ Some* □ None of the CERTIFIED copies of the prioring received.</li> <li>□ received in Application No. (Series Code/Serial Number)</li> </ul>	rity documents ha	ve been	•	•
□ received in this national stage application from the Internation	,			
*Certified copies not received:	<del>,,_</del> -,,		· ·	
Attachment(s)				
• •		tanciaw Summ	ary, PTO-413	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)			•	
• •	□N	otice of Inform	al Patent Application,	PTO-152

Art Unit: 1645

## DETAILED ACTION

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 37-46, drawn to methods of enhancing a protective immune response using a non-toxic double mutant of pertussis toxin, classified in class 424, subclass 282.1.
  - II. Claims 47-54, drawn to vaccine compositions comprising as the adjuvant a non-toxic double mutant of pertussis toxin, classified in class 424, subclass 282.1.
- 2. The inventions are distinct, each from the other because of the following reasons:

  Inventions II and I are related as product and process of use. The inventions can
  be shown to be distinct if either or both of the following can be shown: (1) the process for
- using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the vaccine adjuvant composition as claimed can be used alone as an antigen to make antibodies to pertussis toxin for use in immunotherapy methods or the vaccine composition can be used in methods of intramuscular or oral vaccination processes.
- 3. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.
- 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

775,909 Application/Control Number: 09/127272

Art Unit: 1645

5. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D. June 8, 2002

> Patricia A. Duffy, Ph.D. Primary Examiner Group 1600